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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,903	11/26/2003	Harry M. Meade	GTC-53	2943

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,903	MEADE ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C § 133).
Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63 and 90-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-63 and 90-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 4-11, 14, 16-20, 24, 27-33, 35-41, 44-49, 53, 54, 56-58, and 60-63 are amended, claims 64-89 are canceled, and claims 90-92 are added by amendment, filed 8/25/2006. Claims 1-63 and 90-92 are pending and under consideration.

Election/Restrictions

2. Applicant provisionally elected Group I by telephonic election on 10/15/2005. Applicant formally elected Group I in the response to Non-Final Rejection, filed 8/25/2006.

Information Disclosure Statement

3. The information disclosure statement filed 9/05/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Kabat et al. 1991 is listed as a reference on page 3 of 5 in the IDS, but a copy of this reference was not provided. This reference has not be considered and therefore has been crossed out. Applicant stated that a copy of Kabat et al has been provided in Applicant's response filed 8/25/2006. However, this copy was not found in the application. Therefore, Kabat et al is still not considered.

FR 2,487,642 on page 1 of 5 in the IDS was not considered because it was in French and therefore has been crossed out. Now, only the abstract was been considered.

Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

4. Application failed to comply with Sequence Compliance because specification contained sequences that did not have SEQ ID NOS on page 33 and 34 of the specification. Applicant had amended the specification to include appropriate SEQ ID NOS and therefore the application now conforms with sequence compliance rules.

Claim Objection

5. Claims 33-53 and 55-61, objected to under 37 CFR 1.75(c) as being in improper form because claims 33, 40, 44, 48 are dependent claims that refer to themselves and therefore do not refer to correct independent claims, has been amended to correct the dependency and therefore the objection is withdrawn.

Claims 54 stands objected to under 37 CFR 1.75(c) as being in improper form because claim 54 is a dependent claim that refers to itself and therefore does not refer to the correct independent claim. As a result, dependent claims 33-61 are also misdirected to the wrong claims as well. See MPEP § 608.01(n). Correction of dependent claims to refer to correct claims would be remedial.

Amended claims 21, 53, and 55 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

These claims encompass the same scope as their independent claims because in the process of amending the claims, the identical embodiments were added to the independent claims. Furthermore, it makes their recitation redundant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7
c
90-92

6. Claims 1-63 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,827,690 in view of U.S. Patent No. 5,849, 992.

In Applicant's response to this rejection, filed 8/25/2006, Applicant states that because the instant claims have not been deemed in condition for allowance, and

therefore, the rejection would be considered provisional. They further state that when claims come into condition for allowance Applicant will then consider filing a Terminal Disclaimer to overcome the instant rejection. Applicant's desire to hold this rejection in abeyance is acknowledged. However, the rejection of record is maintained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-63 stand rejected and claims 90-92 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Above claims are drawn to "transgenic mammal" which encompasses humans. Humans are considered non-statutory subject matter.

Applicant traverses this rejection on the ground that the claims have been amended to recite "non-human mammal" and therefore no longer include non-statutory subject matter. It is acknowledged that Applicant did amend the preamble of the claims to recite "non-human mammal". However, the method steps of the claims recite "a transgenic mammal" which still encompasses humans. Therefore the rejection is maintained for claims 1-63 and is extended to newly added claims 90-92, which depend from the rejected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-63 stand rejected and claims 90-92 are under 35 U.S.C. 112, first paragraph; because the specification, while being enabling for a method of producing modified antibodies in the milk of a transgenic cow, goat, mouse, rat, sheep, pig, or rabbit, comprising providing a non-human transgenic mammal whose somatic and germ cells comprise a sequence encoding a mutation selected from the list: (1) a replacement of serine 241 to a proline in an IgG4 hinge region; (2) an alteration that eliminates a N-linked glycosylation site on the CH2 of an IgG heavy chain by replacing an asparagine to a glutamine in the consensus site; (3) a replacement of an amino acid in the hinge region with a cysteine residue; and (4) replacement of the entire hinge region of an IgG4 isotype with the hinge region of another IgG isotype and is operabley linked to a milk specific promoter that directs expression to mammary epithelial cells, does not reasonably provide enablement for making a transgenic mammal producing any modified antibody of any class or subclass, assembled or not assembles, in any transgenic mammal's milk. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant traversed this rejection on the grounds that to make the mutated antibodies of the instant invention would not be undue experimentation and that the

examples enable the instant invention and therefore any experimentation would be considered routine. These arguments are not found persuasive because the breadth of the claims encompassed subject matter not encompassed by the examples taught in the specification. It is acknowledged that the examples are enabling for some of the embodiments encompassed by the claims, such as (1) a replacement of serine 241 to a proline in an IgG4 hinge region; (2) an alteration that eliminates a N-linked glycosylation site on the CH2 of an IgG heavy chain by replacing an asparagine to a glutamine in the consensus site; (3) a replacement of an amino acid in the hinge region with a cysteine residue; and (4) replacement of the entire hinge region of an IgG4 isotype with the hinge region of another IgG isotype. However, the claims read on a greater breadth than these enabled embodiments. For example the claims read on any serine to proline replacement in any isotype and any elimination of N-linked glycosylation of the CH2 domain of any isotype, etc...and any combination of these mutations. However, the novelty of this invention is that the specific mutations provide for the production of whole antibodies in the milk of transgenic mammals. The art does not teach a method of making antibodies that better suited to be produced as whole antibodies in a transgenic animal. Therefore, an artisan would look to the specification for guidance on producing whole antibodies in the milk of transgenic mammals. However, the specification only teaches the specific mutations above that are capable of resulting in whole antibodies in the milk of a transgenic mammal. Therefore, an artisan would not know how to make whole antibodies in the milk of transgenic mammals other than by the specified mutations encompassed in the examples.

Furthermore, neither the specification nor the art provide adequate guidance on mammary biochemistry to produce exogenous antibodies in their milk in compatible conformations to produce whole antibodies. Therefore, there is no general procedure or guidelines that an artisan would be able to follow to make whole antibodies in transgenic milk other than the disclosed examples demonstrated to have worked. So, to use other mutation that result in a whole antibody, an artisan would have to first design new potential mutations that they would hypothetically think would be compatible with the mammary biochemistry of a transgenic mammal, produce the animal with the new mutation, and determine if the resultant antibody were if fact a whole antibody. Therefore, because of a lack of general understanding and guidance of the principles of producing exogenous whole antibodies in the milk of transgenic mammals, it would be undue experimentation for an artisan to use the instant invention with mutation to antibodies other than those specifically described in the specification.

The amendments to the claims also introduce new enablement issues. The amendment to claim encompasses introducing a nucleic acid into a mammalian cell line. This method would encompass nuclear transfer using cell lines. However, the art indicates that transgenic animals produced by nuclear transfer can not be done.

At present, the state of the art is that transgenic animals cannot be produced by transfecting cell lines. Currently, transgenic animals can only be produced from transfecting primary, diploid cell (Zakhartchenko et al. Mol Reprod Dev 54:264-272, 1999. p.268, col 2, par 1 of Discussion, lines 4-15). Zakhartchenko et al. demonstrate successful nuclear transfer in primary mammary fibroblast but failure to sucessfully do

nuclear transfer in MECL mammary cell line using the same method. The differences may be due to chromosomal differences that prevent reprogramming. Furthermore, cell lines are many times polyploidy or aneuploidy and are not effectively been used to produce transgenic animals. Given the art does not provide a method of transfecting a cell line with a construct encoding a desired gene and selecting cell lines that have integrated the transgene into its genome, an artisan would be reliant upon the specification for guidance to use or made the instant invention. No guidance or working examples as to how an artisan would transfect a cell line with a construct encoding a desired gene and selecting cell lines that have integrated the transgene into its genome, therefore an artisan would not know how to make or use the instant invention.

Therefore, given that the breadth of the claims are not enabled by the specification for the reasons discuss above and previously made of record, the instant rejection is maintained. The instant rejection is also extended to new claims 90-92 for the same reasons disclosed above and previously made of record because they depend from the amended claims already deemed to lack enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 32, 62, and 63, rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01, has been amended to include the missing steps. Therefore, the rejection is withdrawn.

Claims 63 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is still drawn to a method that involves "providing a cell" from a transgenic mammal. Applicant did not address these grounds of rejection in the amendment of claims or in the remarks section of the response. Therefore, the rejection of record is maintained.

Claims 32 and 63, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, have been amended to clarify the claim and therefore the rejection of these claims is withdrawn. However, claim 62 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is still drawn to a method that introduces "into a mammal a construct ". A construct cannot be introduced into a mammal directly. It must be introduced into an embryo or cell transferred into an embryo. For these reasons, this claim is considered vague and indefinite and therefore rejection of claim 62 under 112, second paragraph is maintained.

Claim 14, 18, 30, 31, 59, and 60, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been clarified by amendment. Therefore, these rejections are withdrawn.

Amended claims 1-63 and new claims 90-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims disclose a non-human transgenic mammal in the preamble and any transgenic mammal is the method steps of the claims. Therefore is unclear if human or non-human marnmals are intended for the instant method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 23, 32, and 52, rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al (Patent # 5,827,690, Oct 27, 1998) in view of Taylerson et al (Patent

5,985,281, Nov 16, 1999), has been amended and no longer is made obvious by the instant art. Therefore, the rejection is withdrawn.

Applicant traversed this rejection on the general grounds that the art neither teach the embodiments nor render the instant invention obvious and that the amendments of the claims clarify the instant invention. The amendments to the claims now specific the specific alteration to the hinge region be a replacement of a serine with a proline. The art in the instant rejection do no encompass this embodiment, and therefore the rejection is withdrawn.

9. Claims 1 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al (Patent # 5,827,690, Oct 27, 1998) in view of Owen et al (Patent Application # US 6,204,007, March 20, 2001). However, the amendments to claims 32 and 50 overcome the instant rejection and therefore the rejection of 32 and 50 is withdrawn.

Applicant traversed this rejection on the general grounds that the art neither teach the embodiments nor render the instant invention obvious and that the amendments of the claims clarify the instant invention. For claims 1 and 21, Applicant's arguments are not found persuasive. Meade et al provided a method of expressing exogenous antibodies in the milk of transgenic animals. Owen et al teaches a replacement of a serine with a proline in the hinge region and suggests that this alternation will provide for a more stable consistent production of antibodies and reduce the production of alternative conformations of the IGγ4 isotype. Meade et al also

teaches that production of antibodies in transgenic animals will allow for large scale production of antibodies. Therefore, together Meade et al and Owen et al teach a means of producing the claimed antibodies with a serine to proline replacement in the hinge region and the production of antibodies in the milk of transgenic antibodies. They provide a reasonable motivation to do so and a reasonable expectation of success.

Applicant's arguments that the amendments to the claims clarify and overcome the rejection of record is only partly persuasive. The amendments to the claims now specific the specific alteration to the hinge region be a replacement of a serine with a proline. The instant art still encompasses these limitations of claims 1 and 21. Therefore, the art of record still renders claims 1 and 21 obvious. However, amended claims 32 and 50 specific different alterations to the antibodies. Therefore, they are no longer made obvious by the instant art and therefore the rejection of claims 32 and 50 are withdrawn.

10. Claims 1, 12, 15, 16, 18, 20, 32, 41, 44, 45, 47, 49, and 56-58, rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al (Patent # 5,827,690, Oct 27, 1998) in view of Tan et al. (PNAS 87:162-166, 1990), have been amended and therefore the art no longer is obvious over the claims. Therefore the rejection is withdrawn.

Applicant traversed this rejection on the general grounds that the art neither teach the embodiments nor render the instant invention obvious and that the amendments of the claims clarify the instant invention. The amendments to the claims

now specify specific alteration to the hinge region not encompassed by the instant art, and therefore the rejection is withdrawn.

11. Claims 32 and 53-55 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al (Patent # 5,827,690, Oct 27, 1998) in view of Chuang and Morrison (J Immonol 158:724-732, 1997). However, the amendments to claims 1, 24-26 specify different alteration to the antibody to be produces and therefore the art no longer renders claims 1, 24-26 obvious, and therefore the rejection of 1, 24-26 is withdrawn.

Applicant traversed this rejection on the general grounds that the art neither teach the embodiments nor render the instant invention obvious and that the amendments of the claims clarify the instant invention. For claims 32 and 53-55 these arguments are not found persuasive. The amendments to the claims now specify that the alteration to the antibody be to eliminate at least on N-linked glycosylation site on the CH2 region of an antibody's heavy chain region. Chuang and Morrison still teach an Asn263 to Gln substitution in the CH2 domain of and IgA (p. 725, col 1, par 1 under material and methods section). As disclosed in item 9, Meade et al still provides a means of producing transgenic animals that express exogenous antibodies in there milk and a motivation of producing high yields of antibodies. Chuang and Morrison also still provide motivation for this specific alteration because it yields antibodies with enhanced effector function. Therefore, the instant art continues to render claims 32 and 53-55 obvious. Therefore the rejection of claims 32 and 53-55 is maintained.

12. Claim 1 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pollock et al. (J Immuno Methods 231:147-157, 1999) in view of Clark et al. (Biotechnology 7:487-492, 1989).

Applicant traversed this rejection on the general grounds that the art neither teach the embodiments nor render the instant invention obvious and that the amendments of the claims clarify the instant invention. These arguments are not persuasive because the claim 4 is generally drawn to a standard procedure of obtaining from a transgenic mammal and this procedure is standard in the art for any transgenic mammal expressing any protein in their milk as taught by Pollock et al. Therefore, it would be obvious to apply the method of Pollock et al to obtain the milk of from a transgenic animal. Therefore, the rejection is maintained.

13. Claim 1 and 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kutzko et al. (US Patent # 6,268,487, July 2001) in view of Pollock et al. (J Immuno Methods 231:147-157, 1999).

Applicant traversed this rejection on the general grounds that the art neither teach the embodiments nor render the instant invention obvious and that the amendments of the claims clarify the instant invention. These arguments are not persuasive because the claim 4 is generally drawn to a standard procedure of purifying the antibodies from a transgenic mammal and this procedure is standard in the art for any transgenic mammal expressing any protein in their milk as taught by Kutzko et al

and Pollock et al. Therefore, it would be obvious to apply the method of Kutzko et al to obtain the milk of from a transgenic animal. Therefore, the rejection is maintained.

14. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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